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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/038,730	01/02/2002	Robert M. Abrams	269/106 (cont.)	3733

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EXAMINER	
SCHNIZER, RICHARD A	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 05/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,730	ABRAMS ET AL.	
	Examiner	Art Unit	
	Richard Schnizer, Ph. D	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *32-59* is/are pending in the application.

4a) Of the above claim(s) *42,45 and 47-52* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *32-41,43,44,46 and 53-59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/11/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

An amendment was received and entered on 2/15/05.

Claim 60 was canceled as requested.

Claims 32-59 remain pending in the application.

Claims 42, 45, and 47-52 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 4-12-04.

Claims 32-41, 43, 44, 46 and 53-59, drawn to a composition comprising a polymer-forming, or dissolved polymeric, biodegradable material and a biologically active component wherein the biological component is a protein or peptide, are under consideration in this Office Action.

Drawings

No drawings were filed with the application.

Compliance with 37 CFR 1.121

37 CFR 1.121 sets forth the format for amendments to the claims, and requires that all matter added to claims must be indicated by underlining, and material removed must be lined through or bracketed. In the response filed 2/1/05, "c) a mechanical occlusive device" is added to claim 32, but is not underlined. Also "an" is substituted for "the" immediately before the second instance of "anatomical cavity", and "about" is

deleted immediately before "10,000". Applicant is reminded that failure to comply with 37 CFR 1.121 may result in issuance of a notice of noncompliant amendment.

Rejections Withdrawn

The rejection of claims 32-35, 38-41, 44, 46, and 53-59 under 35 U.S.C. 102(e) as being anticipated by Okada is withdrawn in view of Applicant's amendment requiring a mechanical occlusive device.

The rejection of claims 32-41, 43, 44, 46 and 53-59 under 35 U.S.C. 103(a) as being unpatentable over Okada in view of Cragg et al[1], Whalen et al, Cragg et al[2], Greff et al, and Murayama et al (5,891,192, 6 April 1999) is withdrawn in view of Applicant's amendment requiring that a polymer-forming, or dissolved polymeric, biodegradable material must make up about 5-50% by weight of a system comprising a mechanical occlusive device.

Claim Objections

Claim 55 is objected to because "once" is misspelled as "one".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

New Matter

Claims 32-41, 43, 44, 46 and 53-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims have been amended to replace the words "precursor composition" with the word "system", and to require the presence of a mechanical occlusive device in the "system." The amended claims require that the polymer-forming, or dissolved polymeric, biodegradable material of 'a)' must constitute about 5-50% of the weight of the "system", **including** the weight of the mechanical occlusive device. The specification provides no written support for a system comprising a mechanical occlusive device wherein a polymer-forming, or dissolved polymeric, biodegradable material constitutes 5-50% of the weight of **the entire system including the mechanical occlusive device**. Instead the specification supports polymer solutions of 5-50% (w/w) (see page 12, lines 5-15) that may be combined with a mechanical occlusive device, and the originally filed claims support compositions comprising a polymer-forming, or dissolved polymeric, biodegradable material and a biologically active component wherein the polymer-forming, or dissolved polymeric, biodegradable material is present in a concentration of 5-50% by weight. Neither the specification nor claims as filed supports the instant claim amendment.

Closest Prior Art

Evans et al (US Patent 5,702,361, issued 12/30/1997) is the closest prior art of record. Evans taught a system comprising embolizing polymer solutions in a biocompatible solvent and a non-particulate agent such as a metal coil. Preferred biocompatible polymers include cellulose diacetate and ethylene vinyl alcohol copolymer. Cellulose diacetate polymers are either commercially available or can be prepared by art recognized procedures. In a preferred embodiment, the number average molecular weight, as determined by gel permeation chromatography, of the cellulose diacetate composition is from about 25,000 to about 100,000 more preferably from about 50,000 to about 75,000 and still more preferably from about 58,000 to 64,000. See column 5, lines 40-48. Preferably, the polymer composition will comprise from about 2.5 to about 8.0 weight percent of the biocompatible polymer composition based on the total weight of the polymer composition. See column 7, lines 10-18. The reference is silent as to the weight of the non-particulate agent. Both components of the system are considered to be biologically active inasmuch as they cause clot formation. See e.g. column 9, lines 27-33. The particular biocompatible polymer employed is not critical and is selected relative to the viscosity of the resulting polymer solution, the solubility of the biocompatible polymer in the biocompatible solvent, the compatibility of the polymer composition with the non-particulate agent and the like. Such factors are well within the skill of the art. See column 5, lines 34-39. The biocompatible solvent can be an aqueous mixture comprising ethanol. See column 6, lines 44-52. Evans also

taught a method in which the non-particulate agent (e.g., platinum coils) is first introduced to the vascular site to be embolized via conventional catheter technology. After introduction of the non-particulate agent to the vascular site, a sufficient amount of the polymer composition is introduced by conventional means (e.g., catheter delivery under fluoroscopy). See column 8, lines 12-23. Evans also taught kits comprising:
(a) a polymer composition comprising a biocompatible polymer, a biocompatible solvent and a contrast agent; and
(b) a non-particulate agent or plurality of such agents; or
(a) a prepolymer composition comprising a biocompatible prepolymer and a contrast agent; and
(b) a non-particulate agent or plurality of such agents.
Preferably, in either case, the kit further comprises a catheter capable of delivering said polymer or prepolymer composition.

Evans is silent as to the weight of the non-particulate agent, so it is unknown what percent of the weight of the system is accounted for by the polymer, and Evans cannot be applied to the instant claims as a reference under 35 USC 102.

In the event that Applicant amends the claims to overcome the new matter rejection set forth above, it should be noted that it would have been obvious to coat the coils of Evans with fibronectin, in view of the teachings of Murayama et al, of record, because Murayama taught that coating such intralumenal coils led to improved performance. See e.g. column 1, lines 57-67 and column 2, line 64 to column 3, line 8.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Richard Schnizer, whose telephone number is 571-272-0762. The examiner can normally be reached Monday through Friday between the hours of 6:00 AM and 3:30 PM. The examiner is off on alternate Fridays, but is sometimes in the office anyway.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Andrew Wang, can be reached at (571) 272-0811. The official central fax number is 703-872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

(Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Richard Schnizer, Ph.D.

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER